

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

FOREST LABORATORIES, INC., )  
FOREST LABORATORIES HOLDINGS, )  
LTD., MERZ PHARMA GMBH & CO. )  
KGAA, and MERZ PHARMACEUTICALS )  
GMBH, )

Plaintiffs, )

v. )

COBALT LABORATORIES INC., LUPIN )  
PHARMACEUTICALS, INC., LUPIN LTD., )  
ORCHID PHARMACEUTICALS INC., )  
ORCHID CHEMICALS & )  
PHARMACEUTICALS LTD. (d/b/a ORCHID )  
HEALTHCARE), TEVA )  
PHARMACEUTICALS USA, INC., )  
UPSHER-SMITH LABORATORIES, INC., )  
WOCKHARDT USA INC., and )  
WOCKHARDT LIMITED, )

Defendants. )

Civil Action No. 08-0021 (GMS)(LPS)

**JURY TRIAL DEMANDED**

**ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIMS, AND  
JURY DEMAND OF DEFENDANT COBALT LABORATORIES INC.**

Defendant Cobalt Laboratories Inc. ("Cobalt") hereby answers the Complaint of Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively "Plaintiffs") as follows:

**PARTIES**

1. Plaintiff Forest Laboratories, Inc. ("Forest Labs") is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

**ANSWER:** Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

2. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda (referred to herein, together with Forest Laboratories, Inc., as “Forest”).

**ANSWER:** Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

3. Plaintiff Merz Pharma GmbH & Co. KGaA is a German corporation having a principal place of business at Eckenheimer Landstrabe 100, D-60318 Frankfurt am Main, Germany.

**ANSWER:** Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

4. Plaintiff Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstrabe 100, D-60318 Frankfurt am Main, Germany (referred to herein, together with Merz Pharma GmbH & Co. KGaA, as “Merz”).

**ANSWER:** Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

5. Upon information and belief, Defendant Cobalt Laboratories Inc. (“Cobalt”) is a Delaware corporation having a principal place of business at 24840 Tamiami Trail, Bonita Springs, Florida 34134.

**ANSWER:** Admitted.

6. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. (“Lupin Pharma”) is a Virginia corporation, and the wholly-owned subsidiary and agent of Defendant Lupin Ltd., having a principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief, Defendant Lupin Pharma manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

**ANSWER:** Paragraph 6 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without

knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

7. Upon information and belief, Defendant Lupin Ltd. ("Lupin") is an Indian corporation having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Upon information and belief, Defendant Lupin, itself and through its wholly owned subsidiary and agent Defendant Lupin Pharma, manufactures numerous generic drugs for sale and use throughout the United States including in this judicial district.

**ANSWER:** Paragraph 7 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

8. Upon information and belief, Defendant Orchid Pharmaceuticals Inc. ("Orchid Pharma") is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Orchid Chemicals & Pharmaceuticals Ltd., having a principal place of business at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

**ANSWER:** Paragraph 8 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

9. Upon information and belief, Defendant Orchid Chemicals & Pharmaceuticals Ltd. (d/b/a Orchid Healthcare) ("Orchid") is an Indian corporation having a place of business at Orchid Towers, 313 Valluvar Kottam High Road, Nungambakkam, Chennai, Tamil Nadu 600 034 India and a place of business at Plat No. B3-B6 & B11-B14, Sipcot Industrial Park, Irungattukottal, Sriperumbudur (TK) - 602 105, Kancheepuram District, Tamil Nadu, India. Upon information and belief, Defendant Orchid, itself and through its wholly-owned subsidiary and agent Defendant Orchid Pharma, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

**ANSWER:** Paragraph 9 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without

knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

10. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware corporation having a principal place of business at 1090 Horsham Rd., PO Box 1090, North Wales, Pennsylvania 19454.

**ANSWER:** Paragraph 10 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

11. Upon information and belief, Defendant Upsher-Smith Laboratories, Inc. ("Upsher-Smith") is a Minnesota corporation having a principal place of business at 6701 Evenstad Drive, Maple Grove, Minnesota 55369. Upon information and belief, Defendant Upsher-Smith manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

**ANSWER:** Paragraph 11 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

12. Upon information and belief, Defendant Wockhardt USA Inc. ("Wockhardt USA") is a Delaware corporation and the wholly-owned subsidiary and agent of Defendant Wockhardt, having a principal place of business at 75 Ronald Reagan Boulevard, Warwick, NY 10990.

**ANSWER:** Paragraph 12 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

13. Upon information and belief, Defendant Wockhardt Limited ("Wockhardt") is an Indian corporation having a principal place of business at Wockhardt Tower, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Upon information and belief,

Defendant Wockhardt, itself and through its wholly-owned subsidiary and agent Defendant Wockhardt USA, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

**ANSWER:** Paragraph 13 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

#### **NATURE OF THE ACTION**

14. This is a civil action for infringement of United States Patent No. 5,061,703 (“the ‘703 patent”) (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

**ANSWER:** Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Cobalt admits that this action purports to allege infringement of U.S. Patent No. 5,061,703 (“the ‘703 Patent”). Cobalt denies the remaining allegations of this Paragraph.

#### **JURISDICTION AND VENUE**

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Cobalt admits that this Court has subject matter jurisdiction for the claims asserted against Cobalt under 35 U.S.C. § 271(e)(2)(A) only. Cobalt denies the remaining allegations of this Paragraph.

16. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Plaintiff Forest Labs, a Delaware corporation. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

**ANSWER:** Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, and to conserve the resources of the parties and the Court, Cobalt does not contest personal jurisdiction for purposes of this action only. Cobalt denies the remaining allegations of this Paragraph. Cobalt further denies that Cobalt has “committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement.”

17. This Court has personal jurisdiction over Defendant Cobalt by virtue of the fact that, *inter alia*, Cobalt is a Delaware corporation.

**ANSWER:** Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Cobalt admits that it is a Delaware corporation. To conserve the resources of the parties and the Court, Cobalt does not contest personal jurisdiction for purposes of this action only. Cobalt denies the remaining allegations of this paragraph.

18. This Court has personal jurisdiction over Defendant Lupin Pharma by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

**ANSWER:** Paragraph 18 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

19. This Court has personal jurisdiction over Defendant Lupin by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its subsidiary and agent Lupin Pharma.

**ANSWER:** Paragraph 19 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

20. This Court has personal jurisdiction over Defendant Orchid Pharma by virtue of the fact that, *inter alia*, Orchid Pharma is a Delaware corporation.

**ANSWER:** Paragraph 20 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

21. This Court has personal jurisdiction over Defendant Orchid by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Orchid Pharma; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Orchid Pharma.

**ANSWER:** Paragraph 21 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

22. This Court has personal jurisdiction over Defendant Teva by virtue of the fact that, *inter alia*, Teva is a Delaware corporation.

**ANSWER:** Paragraph 22 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

23. This Court has personal jurisdiction over Defendant Upsher-Smith by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

**ANSWER:** Paragraph 23 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.



24. This Court has personal jurisdiction over Defendant Wockhardt USA by virtue of the fact that, *inter alia*, Wockhardt USA is a Delaware corporation.

**ANSWER:** Paragraph 24 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

25. This Court has personal jurisdiction over Defendant Wockhardt by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Wockhardt USA; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Wockhardt USA.

**ANSWER:** Paragraph 25 contains allegations directed toward a Defendant other than Cobalt to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

26. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**ANSWER:** Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, and to conserve the resources of the parties and the Court, Cobalt does not contest venue in this judicial district for purposes of this action only. Cobalt denies the remaining allegations of this Paragraph.

#### **THE PATENT-IN-SUIT**

27. On October 29, 1991, the '703 patent, titled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Merz has been, and continues to be, the sole assignee of the '703 patent since its issuance.

**ANSWER:** Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, Cobalt admits that according to the records of the U.S.



Patent and Trademark Office (“PTO”), on or about October 29, 1991, the PTO issued the ‘703 patent, entitled “Adamantine Derivatives in the Prevention and Treatment of Cerebral Ischemia,” to Joachim Bormann, Markus R. Gold, and Wolfgang Schatton; and that the electronic assignment records of the PTO identify “MERZ PHARMA GMBH & CO. KGAA” as the assignee. Cobalt denies that the ‘703 patent was “duly and legally issued.” Cobalt denies all remaining allegations of Paragraph 27.

28. Forest is the exclusive licensee of the ‘703 patent in the United States. Forest holds New Drug Application (“NDA”) No. 21-487 for Namenda® brand memantine hydrochloride tablets. The ‘703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) for Namenda®.

**ANSWER:** Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, Cobalt admits that the electronic version of the U.S. Food and Drug Administration’s (“FDA”) publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”), identifies “FOREST LABS” as the applicant for approved NDA No. 21-487 for Namenda® (memantine hydrochloride) tablets 5mg and 10mg; and that the electronic version of the Orange Book lists the ‘703 patent in connection with Namenda®. Cobalt denies all remaining allegations of Paragraph 28.

29. Forest is the exclusive distributor of Namenda® in the United States.

**ANSWER:** Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, Cobalt is without knowledge and information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

30. On August 18, 2004, Merz submitted a request to the PTO for reexamination of the ‘703 patent. The PTO issued a reexamination certificate (Exhibit B) for the ‘703 patent on November 7, 2006.

**ANSWER:** Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Cobalt admits that on or about November 7, 2006, the PTO issued a reexamination certificate for the '703 patent. Cobalt denies the remaining allegations of Paragraph 30.

**ACTS GIVING RISE TO THIS ACTION**

**Count I - Infringement Of The '703 Patent By Defendant Cobalt**

31. Upon information and belief, Defendant Cobalt submitted ANDA No. 90-042 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Cobalt's ANDA No. 90-042 seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride ("the Cobalt Generic Products"). Cobalt's ANDA No. 90-042 specifically seeks FDA approval to market the Cobalt Generic Products prior to the expiration of the '703 patent.

**ANSWER:** Cobalt admits that it submitted an ANDA to FDA for Memantine Hydrochloride Tablets, 5 mg and 10 mg, and that such ANDA contains a so-called "Paragraph IV Certification" seeking FDA approval prior to the expiration of the '703 patent. Cobalt denies the remaining allegations of Paragraph 31.

32. Pursuant to §505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Cobalt alleged in ANDA No. 90-042 that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Cobalt Generic Products. Plaintiffs received written notification of ANDA No. 90-042 and its § 505(j)(2)(A)(vii)(IV) allegation on or about December 6, 2007.

**ANSWER:** Cobalt admits its ANDA for Memantine Hydrochloride Tablets, 5 mg and 10 mg, contains a so-called "Paragraph IV Certification," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), stating that the '703 patent is invalid, unenforceable and/or will not be infringed by the manufacture, sale or use of the drug product for which Cobalt submitted its ANDA; and that Forest Laboratories, Inc. and Merz Pharma GmbH & Co. KGaA received written notification of Cobalt's ANDA and Paragraph IV Certification on or about December 6, 2007. Cobalt denies the remaining allegations of Paragraph 32.

33. Cobalt's submission of ANDA No. 90-042 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Cobalt commercially manufactures, uses, offers to sell, sells, or imports any of the Cobalt Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

**ANSWER:** Denied.

34. Cobalt was aware of the '703 patent prior to filing ANDA No. 90-042.

**ANSWER:** Paragraph 34 contains legal conclusions to which no answer is required.

To the extent an answer is required, Cobalt admits that it was aware of the '703 patent prior to filing its ANDA. Cobalt denies that the claims of the '703 patent are valid, and further denies that it infringes any valid claim of the '703 patent. Cobalt denies the remaining allegations of Paragraph 34.

35. Cobalt's actions render this an exceptional case under 35 U.S.C. § 285.

**ANSWER:** Denied.

36. Plaintiffs will be irreparably harmed by Cobalt's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

#### **Counts II – VI: Paragraphs 37 – 72**

Paragraphs 37 – 72 (Counts II – VI) contain allegations directed solely toward other defendants to which no answer is required. To the extent an answer is required, Cobalt denies all such allegations.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs pray for judgment as follows:

- A. That all Defendants have infringed the '703 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' respective ANDAs identified in this Complaint shall not be earlier than the expiration date of the '703 patent, including any extensions;
- C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined

from commercially manufacturing, using, offering for sale, selling, or importing any of the proposed generic versions of Plaintiffs' Namenda® brand product identified in this Complaint and any other product that infringes or induces or contributes to the infringement of the '703 patent, prior to the expiration of the '703 patent, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

**ANSWER:** Cobalt denies that Plaintiffs are entitled to any of the relief prayed for in paragraphs (A) through (F), above, or to any relief whatsoever, and further requests that judgment be entered in favor of Cobalt, dismissing Plaintiffs' Complaint with prejudice, awarding Cobalt its attorneys' fees and costs incurred in defending this action under 35 U.S.C. § 285, and granting such further relief as this Court may deem just and proper.

Cobalt further denies each allegation not specifically admitted or otherwise responded to herein.

### **SEPARATE DEFENSES**

Without prejudice to the denials set forth in its Answer, without admitting any allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Cobalt asserts the following defenses to the Complaint:

#### **First Defense**

The claims of the '703 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

### **Second Defense**

The manufacture, sale, use, offer for sale, or importation of Cobalt's proposed memantine product that is the subject of its ANDA would not infringe, either directly or indirectly, any valid and enforceable claim of the '703 patent, either literally or under the doctrine of equivalents.

### **Third Defense**

The claims of the '703 patent are unenforceable at least past April 11, 2010.

### **Fourth Defense**

The Court lacks subject matter jurisdiction over all claims other than those asserted under 35 U.S.C. § 271(e)(2)(A).

### **Fifth Defense**

The Complaint fails to state a claim upon which relief can be granted.

### **Sixth Defense**

Any additional defenses or counterclaims that discovery may reveal.

## **COUNTERCLAIMS**

Defendant/Counterclaim Plaintiff, Cobalt Laboratories Inc. ("Cobalt"), for its Counterclaims against Plaintiffs/Counterclaim Defendants, Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively "Plaintiffs"), alleges as follows:

### **The Parties**

1. Cobalt Laboratories Inc. is a Delaware corporation, having a place of business at 24840 Tamiami Trail, Bonita Springs, Florida 34134.

2. Plaintiff Forest Laboratories, Inc. purports to be a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

3. Plaintiff Forest Laboratories Holdings, Ltd. purports to be an Irish corporation having a principal place of business at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda.

4. Plaintiff Merz Pharma GmbH & Co. KGaA purports to be a German Corporation having a principal place of business at Eckenheimer Landstrabe 100, D-60318 Frankfurt am Main, Germany.

5. Plaintiff Merz Pharmaceuticals GmbH purports to be a German corporation having a principal place of business at Eckenheimer Landstrabe 100, D-60318 Frankfurt am Main, Germany.

#### **Jurisdiction and Venue**

6. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Cobalt in this District, and/or because Plaintiffs conduct substantial business in this District.

9. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

**Patent-in-Suit**

10. On or about October 29, 1991, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 5,061,703 (“the ‘703 patent”), entitled “*Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia*,” to Joachim Bormann, Markus R. Gold, and Wolfgang Schatton.

11. Plaintiffs purport and claim to own, and to have the right to enforce, the ‘703 patent.

12. On or about January 10, 2008, Plaintiffs filed a Complaint against Cobalt in this District alleging infringement of the ‘703 patent under 35 U.S.C. § 271(e)(2)(A).

**COUNT I**  
**(Declaration of Non-Infringement of the ‘703 Patent)**

13. Cobalt realleges and incorporates by reference the allegations of Paragraphs 1-12.

14. A present, genuine, and justiciable controversy exists between Plaintiffs and Defendant Cobalt regarding, *inter alia*, the non-infringement of any valid or enforceable claim of the ‘703 patent.

15. The manufacture, use, or sale of the memantine hydrochloride tablets, 5 mg and 10 mg, that are the subject of Cobalt’s ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the ‘703 patent, either directly or indirectly.

16. Cobalt is entitled to a declaration that the manufacture, use, sale, offer for sale, and/or importation of the memantine hydrochloride tablets, 5 mg and 10 mg, that are the subject of Cobalt’s ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the ‘703 patent, either directly or indirectly.



**COUNT II**  
**(Declaration of Invalidity of the '703 Patent)**

17. Cobalt realleges and incorporates by reference the allegations of Paragraphs 1-16.

18. A present, genuine, and justiciable controversy exists between Plaintiffs and Cobalt regarding, *inter alia*, the validity of the claims of the '703 patent.

19. The claims of the '703 patent are invalid under one or more provisions of Title 35 of the United States Patent Code.

20. Cobalt is entitled to a declaration that the claims of the '703 patent are invalid.

**COUNT III**  
**(Declaration of Unenforceability of the '703 Patent)**

21. Cobalt realleges and incorporates by reference the allegations of Paragraphs 1-20.

22. A present, genuine, and justiciable controversy exists between Plaintiffs and Defendant Cobalt regarding, *inter alia*, the enforceability of the claims of the '703 patent past April 11, 2010.

23. The claims of the '703 patent are unenforceable at least past April 11, 2010.

24. Cobalt is entitled to a declaration that the claims of the '703 patent are unenforceable at least past April 11, 2010.

**PRAYER FOR RELIEF**

WHEREFORE, Cobalt respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs as follows:

- (a) Declaring that the manufacture, use, or sale of the memantine hydrochloride tablets, 5 mg and 10 mg, that are the subject of Cobalt's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '703 patent;

- (b) Declaring that the claims of the '703 patent are invalid;
- (c) Declaring that the claims of the '703 patent are unenforceable at least past April 11, 2010;
- (d) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Cobalt its attorneys' fees, costs, and expenses in this action; and
- (e) Awarding Cobalt any further and additional relief as the Court deems just and proper.

**JURY DEMAND**

Cobalt hereby demands a trial by jury on all claims, defenses, and counterclaims so triable.

Dated: March 3, 2008

Respectfully submitted,

COBALT LABORATORIES INC.

By: 

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